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VE EXPRESS MAIL LABEL NO.: EV 333487080 US

**PATENT** 

**Attorney Docket No. 29191.707.201** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Jonathan C. HELLER et al.

Art Unit: 2855

Application No.: 10/645,863

Filed: August 20, 2003

Title: System of analyzing complex mixtures of biological and other fluids to identify biological state information

PATENT APPLICATION

Art Unit: 2855

Examiner: Not yet assigned

Of biological and other fluids to identify biological state information

PATENT APPLICATION

Art Unit: 2855

Examiner: Not yet assigned

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

$\boxtimes$	This s	This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:							
		(1)	It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  OR						
		(2)	It is being filed within 3 months of entry of a national stage OR						
	$\boxtimes$	(3)	It is being filed before the mail date of the first Office Action on the merits OR						
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	the fil nation a first	37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:							
		a certif	fication as specified in §1.97(e) is provided below; or						
			of \$180.00 as set forth in \$1.17(p) is authorized below, enclosed, or included ne payment of other papers filed together with this statement.						
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	A.	a certif	fication as specified in §1.97(e) is completed below; and						
,	B.	-	tion under 37 C.F.R. §1.97(d) requesting consideration of this statement is ted herewith; and						
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	Copie herew		ch of the references listed on the attached Form PTO/SB/08 are enclosed						
$\boxtimes$	Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXTHAT:								
			w of the voluminous nature of references, and the likelihood that these are available to the Examiner in the file history of the parent application No. ), copies are not enclosed herewith.						
			If any of the foregoing publications are not available to the Examiner,						

		Copies of only foreign patent documents accordance with 37 CFR 1.98 (a)(2). (application publication listed on the atta because this U.S. patent application was file application has entered the national stage up USPTO waiver of requirement under 37 CF	The U.S. patents and each U.S. patent ched Form PTO-1449 are not enclosed ed after June 30, 2003 or this international ader 35 USC §371 after June 30, 2003 (see
	There	are no listed references which are not in the I	English language
	The re	elevance of those listed references which are r	not in the English language is as follows:
		hed are copies of search report(s) from correction of the many many many many many many many many	1
	Attach relevar	hed are the following non-published pending ant.	patent applications which may be deemed
	fees of	authorization. The Commissioner is hereby a of \$0.00 and charge any additional fees or creaturization to Deposit Account No. 23-2415 (E	edit any overpayment associated with this
		Respe	ctfully submitted,
		WILS	ON SONSINI GOODRICH & ROSATI
Dated:		9/23/04 By: U	Um Pathy
Palo A (650)	493 <b>-</b> 930	l Road A 94304-1050	P. Peter Eng, Reg. No. 39,666

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known Application Number 10/645,863 08/20/2003 Filing Date First Named Inventor Jonathan C. HELLER Art Unit 2855 **Examiner Name** Not yet assigned 29191.707.201 Attorney Docket Number

		U.S. F	ATENT DOCU	MENTS		
Examiner Cite Initials* No.1		Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		US-2002/0048777	04/25/2002	Ali et al.		
	·	US-2002/0127237	09/12/2002	Salceda et al.		
		US-2002/0177140	11/28/2002	Salceda et al.		
		US-2003/0039983 ·	02/27/2003	Sun et al.		
		US-2003/0064377	04/03/2003	Sun et al.		
		US-2003/0078739	04/24/2003	Norton et al.		
		US-2003/0111596	06/19/2003	Becker et al.		
		US-2003/0129760	07/10/2003	Aguilera et al.		
		US-2003/0175707	09/18/2003	Sun et al.		
		US-2003/0194739	10/16/2003	Ali et al.		
		US-2003/0199001	10/23/2003	Pitt et al.		
		US-2004/0053333	03/18/2004	Hitt et al.		
*		US-6,593,298	07/15/2003	Jackowski et al.		
		US-6,599,877	07/29/2003	Jackowski et al.		
		US-6,602,855	08/05/2003	Jackowski et al.		
		US-6,617,308	09/09/2003	Jackowski et al.		
		US-6,620,786	09/16/2003	Jackowski et al.		
		US-6,620,787	09/16/2003	Jackowski et al.		
		US-6,627,606	09/30/2003	Jackowski et al.		
·		US-6,627,607	09/30/2003	Jackowski et al.		
		US-6,627,608	09/30/2003	Jackowski et al.		
		US-6,677,303	01/13/2004	Jackowski et al.		
		US-6,703,366	03/09/2004	Jackowski et al.		
		US-6,756,476	06/29/2004	Jackowski et al.		

Signature \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Complete if Known		
Substitute fo	or form 1449	9/PTO		Application Number	10/645,863	
INFORM	IATION	DISC	LOSURE	Filing Date	08/20/2003	
STATEMENT BY APPLICANT				First Named Inventor	Jonathan C. HELLER	
(Use as	many sheet	ts as neo	cessary)	Art Unit	2855	
				Examiner Name	Not yet assigned	
Sheet	2	of	3	Attorney Docket Number	29191.707.201	

			PATENT DO	CUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
,		EP 0881494	12/02/1998	Boehringer Mannheim GmbH		X
		WO 00/23111	04/27/2000	Diadexus LLC		
		WO 03/058198	07/17/2003	Ciphergen Biosystems, Inc.		
		WO 03/086445	10/23/2003	Ciphergen Biosystems, Inc.		
		WO 03/089937	10/30/2003	Thermo Finnigan, LLC		
		WO 2004/012588	02/12/2004	The Johns Hopkins University; Ciphergen Biosystems, Inc.		
		WO 2004/013609	02/12/2004	The Johns Hopkins University; Ciphergen Biosystems, Inc.		
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Substitute for	or form 144	49/PTO		Application Number	10/645,863	
INFORM	IATION	DISC	CLOSURE	Filing Date	08/20/2003	
			PLICANT	First Named Inventor	Jonathan C. HELLER	
(Use d	is many shee	ets as nec	cessary)	Art Unit	2855	
				Examiner Name	Not yet assigned	
Sheet	3	of	3	Attorney Docket Number	29191.707.201	

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the mitem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number publisher, city and/or country where published.						
		AURIOLA, Seppo et al., "Enhancement of sample loadings for the analysis of oligosaccharides isolated from <i>Pseudomonas aeruginosa</i> using transient isotachophoresis – electrospray – mass spectrometry". <i>Electrophoresis</i> (1998), 19:2665-2676.	_				
		FIGEYS, Daniel et al., "High sensitivity analysis of proteins and peptides by capillary electrophoresistandem mass spectrometry: recent developments in technology and applications". <i>Electrophoresis</i> , (1998), 19:885-892.					
		GUO, Xu et al., "Analysis of metallonthioneins by means of capillary electrophoresis coupled to electrospray mass spectrometry with sheathless interfacing" <i>Rapid Commun. Mass Spectrom.</i> (1999), 13:500-507.					
		KAISER, Thorsten et al., "Capillary electrophoresis coupled to mass spectrometry to establish polypeptide patterns in dialysis fluids". <i>Journal of Chromatography A</i> (2003), 1013:157-171.					
		NEUSUB, Christian et al., "A robust approach for the analysis of peptides in the low femtomole range by capillary electrophoresis-tandem mass spectrometry". <i>Electrophoresis</i> (2002), 23:3149-3159.					
		RHODE, E. et al., "Comparison of protein mixtures in aqueous humor by membrane preconcentration – capillary electrophoresis – mass spectrometry". <i>Electrophoresis</i> (1998), 19:2361-2370.					
		STROINK, Thom et al., "On-line coupling of size exclusion and capillary zone electrophoresis via a reversed-phase C18 trapping column for the analysis of structurally related enkephalines in cerebrospinal fluid". Electrophoresis (2003), 24:897-903.					
		WITTKE, Stefan et al., "Determination of peptides and proteins in human urine with capillary electrophoresis-mass spectrometry, a suitable tool for the establishment of new diagnostic markers". Journal of Chromatography A (2003), 1013:173-181.					

Examiner	Date	
signature	Considered	·

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

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